No. 89-243

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, Inc.,

Respondent.

BRIEF FOR AMICUS CURIAE THE PROCTER & GAMBLE COMPANY IN SUPPORT OF PETITIONER ELI LILLY AND COMPANY

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The Procter & Gamble Company ("P&G") files this *amicus curiae* brief in support of Petitioner, Eli Lilly and Company ("Lilly"), to reverse the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989[1]

INTEREST OF THE AMICUS CURIAE

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products and medical devices which are subject to regulation by the Food and Drug Administration ("FDA").[2] P&G also is engaged in significant

[1] P&G has received the consent of both parties for the filing of this brief. Copies of the letters granting said consent have been filed with the clerk.

[2] P&G is *not* a competitor of petitioner or respondent or their subsidiaries, in the field involving the medical devices of this lawsuit.

research and development in these areas. P&G relies substantially upon the patent system for protecting its hard-earned inventions that result from its investments and research efforts.

Although the type of product at issue in this case is medical devices, the Court of Appeals' holding directly affects a much broader range of products. The Court of Appeals stated:

> Accordingly, we hold that Section 271(e)(1) allows a party to make, use or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

(Pet. App. 7a)[3] (emphasis in original).

Thus, the Court of Appeals' decision erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives, as well as medical devices. The decision has significant business impact and will reduce the incentive for P&G and similarly situated companies to invest in innovation in these important fields.

For example, safety tests typically costing millions of dollars need to be conducted by P&G to obtain FDA approval of its patented food additive products. Such tests may take from five to fifteen years or more to complete.[4] It can take another two or three years or more to obtain FDA approval for a food additive or color additive after filing a petition for approval with the FDA.

After P&G has paved the way for competitors by obtaining FDA approval for these pioneering inventions, competitors,

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[3] "Pet. App. 7a" refers to page 7a of the appendix of Lilly's Petition for Certiorari. P&G will refer to petitioner's appendix on several occasions using the same citation form.

[4] P&G has filed for FDA approval for a food additive called olestra, which is a fat substitute product which enbodies inventions which are the subject of existing and pending patents. The safety testing for olestra has taken nearly fifteen years. P&G's petition has been pending for over two years.

in spite of any P&G patents, can use immediately the patented inventions in research conducted to obtain FDA approval for new uses for these inventions under the Court of Appeals' interpretation of Section 271(e)(1). This can lead to competitive advantages for P&G's competitors even though they did not undertake the substantial risk and expense in inventing and then patenting and obtaining original FDA approval for the pioneering inventions. Competitors will also be permitted to conduct testing to obain food or color additive approval of compounds which have been patented by P&G, but for which P&G has not sought approval. In either case, P&G loses exclusive rights to the control of its patented inventions in important research areas. The economic impact is substantial since P&G is deprived of exclusivity in the development of new, potentially important uses for its patented inventions. The net effect is to lessen the incentive for P&G and other innovative companies to invent and invest in pioneering products.

P&G, accordingly, has a strong interest in having this Court correct the erroneous Court of Appeals' decision and restore the full scope of patent protection for food and color additive products (as well as medical devices).

Since the controversy in this case relates to medical devices, it is expected that arguments of the Parties will focus on a comparison between drugs and medical devices, their respective regulatory approval procedures, and how such comparison relates to the intent of Congress in enacting 35 U.S.C. § 271(e)(1). Regulatory procedures for food additives and color additives are different from either drugs or medical devices. Therefore, it is believed that P&G's arguments relating to food additives and color additives will provide added assistance to the Court in understanding why Congress provided a patent infringement exemption for regulatory testing of drugs only, when it enacted 35 U.S.C. § 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984.

SUMMARY OF ARGUMENT

It is clear from the language of 35 U.S.C. § 271(e)(1) and its legislative history that the immunity from infringement which the statute provides for activities conducted to obtain approval to market FDA-regulated products is applicable only to drugs.

The only type of regulated product mentioned in the statute is drugs (and veterinary biological products added by subsequent amendment).

Congress' objective in enacting Title I of The Drug Price Competition and Patent Term Restoration Act of 1984 was to provide for the prompt marketing of generic copies of patented drugs upon expiration of the patents. In order to accomplish this, Congress provided in Title I, an abbreviated procedure for regulatory testing of generic copies of approved drugs, and since regulatory testing of patented drugs during the life of a patent had previously been held to be patent infringement, Congress also enacted Section 271(e)(1) as part of Title I in order to exempt such testing of drugs from patent infringement.

Congress did not modify the procedures for regulatory approval of medical devices, food additives and color additives, nor did it address any patent infringement issues relating to said procedures. These products present regulatory considerations which are different from drugs.

With respect to food additives, the party seeking initial approval files a petition with the FDA proposing the issuance of a regulation prescribing the conditions under which the additive is to be used. The petition is supported with appropriate test data, chemical data, etc. to establish safety and technical effect. When a regulation is subsequently issued which governs the use of the food additive, any party may market its own copy of the approved additive product in conformance with the regulation, i.e., the copier of the approved food additive may markedt its copy without any requirement to obtain prior approval. The situation is similar for color additives. If the food or color additive is the subject of a patent, the copier can begin marketing as soon as the patent expires. Thus, in the case of food and color additives, and contrary to the case with drugs, there is no need for generic copiers to conduct regulatory testing during the life of a patent in order to market a generic copy of an approved additive in accordance with the regulation governing its approval. It is readily apparent, therefore, that the objective which caused Congress to enact Section 271(e)(1), i.e., to provide a means by which copies of approved, patented drugs would become available promptly upon expiration of the patent, is in no way applicable to food or color additives. This situation already existed with respect to these products prior to the enactment of Section 271(e)(1).

Under the Court of Appeals holding, the generic copier, in addition to continuing to have the benefit of a completely "free ride" on the regulatory approval obtained by the patentee of a food or color additive product, will now also be permitted to conduct regulatory testing of the patented, previously approved additive product to seek issuance of new or modified regulations to govern new or expanded uses of it. Also, non-patentees will be permitted to conduct testing to obtain food or color additive approval of patented compounds which have not previously been approved, which could then be sold in competition with other products of the patentee as soon as the relevant patents expire. Both types of testing during the term of a patent are abridgements of the exclusive rights of patentees to control the conduct of commercially motivated research on their patented inventions. An intent to abridge such valuable rights of patentees should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case.

ARGUMENT

A. It Is Clear From the Language of the Statute and Legislative History That Congress Intended Section 271(e)(1) to Apply Only to Drugs

The Court of Appeals in this case determined that infringing medical devices, and other nondrug, FDA-regulated products are entitled to the non-infringement exemption which is provided to drugs under 35 U.S.C. § 271(e)(1) for testing which is conducted to obtain information to be submitted to the FDA for regulatory purposes. It is P&G's position that the Court of Appeals' decision is contrary to the clear wording of the statute, inconsistent with the intent of Congress, and should be reversed.

Notwithstanding that 35 U.S.C. § 271(e)(1) clearly specifies that otherwise infringing acts which are undertaken:

> ". . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture use or sale of *drugs*. . . ." (emphasis added)[5]

are exempt from liability for infringement, the Court of Appeals concluded that there was ambiguity in the statute. The Court then proceeded to conclude that it was the intent of Congress that the exemption should, in effect, extend to any product regulated by the Food & Drug Administration.

The Court of Appeals' decision came as a surprise to P&G. To P&G's knowledge, no one, either in commentary or during the legislative process, had ever read the statutory language of 35 U.S.C. § 271(e)(1) the way the Court of Appeals reads it, *i.e.*, to apply to all products (in addition to drugs and veterinary biological products) regulated by the

[5] The statute was amended in 1988 to add the words "or veterinary biological products" after "drugs", however, the Court of Appeals stated that this amendment did not affect it's analysis in the present case. Pet. App. 4a, Note 4.

FDA.[6] In addition, Senator Orrin G. Hatch (principal author of the Senate Bill that enacted 35 U.S.C. § 271(e)(1) into law) and Representative Carlos J. Moorhead (primary floor manager of that legilsation in the House of Representatives), in an *amicus* brief in support of Lilly's petition for certiorari in this case, expressed their view that Congress intended Section 271(e)(1) to apply only to drugs.

The pertinent legislative history is contained in two House of Representatives Committee Reports, Parts 1 and 2 of H.R. Report 857, 98th Congress, 2nd Sess. (1984), hereinafter "The Committee Reports". These reports show the statute was intended to be specific to drugs. The motivation for the enactment of Section 271(e)(1) was Congress' desire that generic copies of patented, approved drugs be made available to the public promptly upon expiration of the patents on the drugs (Committee Reports Part 1, at 14 and 15.)

Concurrently with the enactment of 35 U.S.C. § 271(e)(1), Congress enacted 21 U.S.C. § 355(j)(1),[7] which provided for an abbreviated procedure for approving generic copies of previously approved drugs. Under this procedure, instead of the full safety and efficacy testing required for a new drug, only testing to demonstrate bioequivalence of the generic copy to the approved drug need be done.

[6] *Compare* Goldstein, *The Drug Price Competition and Patent Term Restoration Act of 1984 Title II — Patent Extension Provisions*, 40 Food Drug Cosm. L.J. 363, 367 (1985) ("[W]hile the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."); Flannery & Hutt, *Balancing Competition and Patent Restoration in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*. 40 Food Drug Cosm. L.J. 269, 307 (1985) (Section 271(e)(1) "dose not include medical devices . . . food additives, color additives, or other related activities.")

[7] 35 U.S.C. § 271(e)(1) and 21 U.S.C. § 355(j)(1) were both enacted into law as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

In the case of *Roche* v. *Bolar*[8] regulatory testing of generic copies of patented drugs during the life of the patent had been held to be patent infringement, in that such testing was for "commercial purposes" and therefore not within the experimental use exception. Therefore, the only way for Congress to fully accomplish its objective of enabling generic copies of patented drugs to become promptly available upon patent expiration, was to grant an exemption from infringement for such testing of drugs.

The above-referenced Committee Reports are replete with statements indicating that it was Congress' intent that Section 271(e)(1) was to be specific to drugs. *See, e.g., id.*, Part 1, at 15 ("it is not an act of patent infringement for a *generic drug*maker to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added); *id.*, Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval for *the drug*." (emphasis added)); *id.*, Part 1 at 45 ("The purpose of Section 271(e)(1) and (2) is to establish that experimentation with *a patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." (emphasis added); *id.*, Part 2 at 6 (". . . the other feature of the *drug* patent part of the bill is to statutorily modify the rules with respect to patent infringement"); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to certain veterinary products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2nd Sess. 13 (1986) (emphasis added).

There is nothing in the legislative history to indicate that Congress intended this statute to affect patents on any type of product other than drugs. The Court of Appeals did not cite any language from the legislative history (because there is

[8] *Roche Products Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

none), which states in words or substance that FDA-regulated medical devices, food additives, color additives, and other non-drug products fall within the exemption of Section 271(e)(1). The Court of Appeals instead, reasoned that since 35 U.S.C. § 156, which provides for extension of the patent term for drugs, medical devices, food additives and color additives whose marketing has been delayed by regulatory review, was passed along with Section 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984, it must have been Congress' intent that the infringement exemption of Section 271(e)(1) apply to medical devices (and food and color additives) as well as drugs (Pet. App. 7a).

B. The Court of Appeals Failed to Recognize the Regulatory Differences Between Drugs and Other FDA-Regulated Products, and Thereby Failed to Understand Why Congress Limited Section 271(e)(1) to Drugs, Notwithstanding The Granting of Patent Term Restoration to Drugs, Medical Devices and Food and Color Additives in 35 U.S.C. § 156.

The over-simplified reasoning by the Court of Appeals fails to take into account (as Congress surely did) the totally different regulatory considerations applicable to drugs on the one hand and to medical devices, food additives and color additives on the other. When enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Congress modified the procedures for regulatory testing of drugs, but not for medical devices, food additives or color additives, nor did Congress address any patent infringement issues relating to these procedures for these latter three types of products. It is expected that considerations relating to drug vs. medical device comparison will be thoroughly dealt with in Lilly's brief. The comparison of drugs vs. food additives and color additives will be dealt with here.

Approval of a new drug requires testing to establish proof of safety and efficacy. Such testing is very cumbersome and

expensive, especially with respect to efficacy, since efficacy must be established in clinical tests on humans afflicted with the illness for which the drug is indicated. Once a drug has been approved in this manner, the generic company can now obtain approval of its copy of the approved drug by testing the copy against the approved drug for bioequivalence. This is done by administering the generic copy to a limited number of human subjects (who usually do not have the illness for which the drug is indicated) and, in the same test, administering the previously approved drug to human test subjects. A determination is then made as to whether the rate and extent of absorption of the generic copy and that of the approved drug are equivalent. *Cf.* 21 U.S.C. § 355(j)(7) (definitions of bioavailability and bioequivalence). Upon submission of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of an abbreviated new drug application submitted pursuant to 21 U.S.C. § 355(j)(1).[9]

The main effect of Section 271(e)(1) in the context of drugs is to allow the completion of such bioequivalence testing of a generic copy of a patented drug prior to patent expiration so that marketing of the copy can begin promptly upon expiration of the patent on the originally approved drug. Although Section 271(e)(1) would also allow a non-patentee to undertake full safety and efficacy testing for drug approval of patented compounds which had not been previously approved for drug use, the ordinary practice of a non-patentee drug manufacturer is to copy a compound upon which the patentee has already obtained approval for drug use, and then obtain approval of the copy by bioequivalence testing. Drug testing that would involve infringement of a patent, but would not involve testing of a generic copy of a previously approved drug, would be extremely rare.

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[9] An alternative procedure for generic copies of some drugs approved after 1962 is the submission of a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b)(2).

The approval of food additives is provided for in 21 U.S.C. § 348. Under this statute a party wishing to gain approval for a new food additive files a petition with the FDA proposing the issuance of a regulation prescribing the conditions under which the additive may be used. The petitioner provides the FDA with pertinent data pertaining to the chemical identity of the additive, conditions of proposed use, intended physical and technical effect, methods to analyze for the presence of the additive in food, and data concerning the safety of the additive, Cf. 21 U.S.C. § 348(b)(2). See generally, J. O'Reilly, Vol. 1, *Food and Drug Administration*, Ch. 11 (1989 Supp.).

When a regulation is issued which governs the use of the food additive, any party may market its own product in conformance with the regulation, Cf. 21 U.S.C. § 348(a)(2); i.e., a copier of the approved product may market its copy without any requirement to obtain separate approval. Thus, in the case of a patented, approved food additive, the copier of the additive can begin marketing its copy promptly upon expiration of the patent without any requirement to obtain prior FDA approval. There is no need to conduct any testing for regulatory purposes during the life of the patent.

This is also true of color additives, which are regulated by listing and certification under 21 U.S.C. § 376, i.e., there is no requirement of a copier of an approved color additive to have its copy of the said additive approved before marketing it in accordance with the regulations governing use of the additive. If the additive is patented, the copier can begin marketing its copy promptly upon expiration of the patent.

It is readily apparent, therefore that the objective which Congress sought when enacting Section 271(e)(1), i.e., to provide a means by which copies of patented *drugs* would become available promptly upon expiration of the patent, is in no way applicable to food and color additives. This situation already existed with respect to food and color additives *prior* to the enactment of Section 271(e)(1).

The Court of Appeals' interpretation of the Section

271(e)(1) has a significant negative impact on the rights of patentees of food additive and color additive inventions. Under the Court's holding the generic copier, in addition to continuing to have the benefit of a completely "free ride" on the regulatory approval obtained by a patentee of a food or color additive product, will now also be permitted to conduct regulatory testing of the patented, previously approved, additive product to seek issuance of new or modified regulations to govern new or expanded uses of it. Also, non-patentees will be permitted to conduct testing to obtain food or color additive approval of patented compounds which have not previously been approved, which could then be sold in competition with other products of the patentee as soon as the relevant patent expires. Both types of testing during the life of the patent are abridgements of the exclusive rights of patentees to conduct commercially motivated research on their patented inventions during the patent term. An intent to abridge such valuable rights of patentees should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case.

It is erroneous to infer, as the Court of Appeals has done, that since 35 U.S.C. § 156 (providing extension of the term of patents on drugs, medical devices, food additives and color additives to compensate for time consumed in regulatory testing and review) was enacted into law along with 35 U.S.C. § 271(e)(1), it was the intent of Congress that exemption for infringement under Section 271(e)(1) should be applicable to medical devices, food additives and color additives as well as drugs. The two statutes involved entirely independent objectives. They were not "companions" as the Court of Appeals referred to them[10]. In order to satisfy the policy of

[10] Section 271(e)(1) was enacted along with 21 U.S.C. § 355(j)(1) (abbreviated procedure for approving generic drugs) under Title I of The Drug Price Competition and Patent Term Restoration Act of 1984. 35 U.S.C. § 156 (patent term restoration) was enacted under Title II of the Act.

stimulating research in the fields of drugs, medical devices, food additives, and color additives, Congress deemed it necessary to compensate innovators for the time effectively lost from the patent term because of the need for regulatory testing and review. This was accomplished by enactment of 35 U.S.C. § 156. In order to satisfy the policy of hastening the availability of low cost generic copies of approved drugs to the public, it was necessary to provide for an abbreviated procedure for testing copies of approved drugs. Since regulatory testing during the life of the patent had previously been held in *Roche* v. *Bolar*[11] to be patent infringement, it was necessary for Congress to enact Section 271(e)(1) in order to exempt the regulatory testing of generic copies of drugs from infringement.

[11] Id. Note 8.

CONCLUSION

The Court of Appeals decision is erroneous. The Court's interpretation of Section 271(e)(1) significantly abridges the exclusive rights of patentees of medical devices, food additives and color additives, thereby reducing the incentive for innovation and investment in these important fields. An intent to abridge such valuable rights should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case. The Court of Appeals decision should be *reversed*.

Respectfully submitted,

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